PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference cu2003/286	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/CU2004/000016	International filing date *(day/month/year)* 02.12.2004	Priority date *(day/month/year)* 03.12.2003
International Patent Classification (IPC) or national classification and IPC C07K14/22, A61K39/095, C12N15/31, A61K39/39, A61K48/00, G01N33/569		
Applicant CENTRO DE INGENIERIA GENETICA Y BIOTECNOLOGIAet al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.08.2005	31.10.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Groenendijk, M Telephone No. +31 70 340-3715

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CU2004/000016

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-21 as originally filed

Sequence listings part of the description, Pages

21-25 as originally filed

Claims, Numbers

1-31 as originally filed

Drawings, Sheets

1/14-14/14 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 30-31 as to IA

because:

☒ the said international application, or the said claims Nos. 30-31 as to IA relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6-8,14,16,17,24,25
	No:	Claims	1-5,9-13,15,18-23,26-31
Inventive step (IS)	Yes:	Claims	6-8
	No:	Claims	1-5,9-31
Industrial applicability (IA)	Yes:	Claims	1-29
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment on

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional observations, if necessary:

Re Item III.

Claims 30-31 encompass subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

Reference is made to the following documents:

D1 : WO 99/57280 A (CHIRON CORPORATION; THE INSTITUTE FOR GENOMIC RESEARCH; FRASER, CLAIRE) 11 November 1999 (1999-11-11)
D2 : WO 01/37863 A (CHIRON SPA; GIULIANI, MARZIA, MONICA; PIZZA, MARIAGRAZIA; RAPPUOLI, RI) 31 May 2001 (2001-05-31)
D3: WO 01/31019 A (CHIRON SPA) 3 May 2001

I.Novelty and inventive step.

1)D1 discloses a polypeptide (NMB0928) having (i.e. comprising) the polypeptide sequence as defined in SEQ ID No.4 of the present application and the encoding DNA sequence (see sequences 1521 and 1522). Furthermore D1 mentions, inter alia, the use of said compounds in vaccines and for diagnostic purposes (claims 1-18).
2)Document D2 discloses the polypeptide with SEQ ID No. 1522 as defined in D1 and mentions its use in combination with additional antigenic compounds (see particularly claims 1 and 2).
3)D3 discloses fragments of the present polypeptide defined by SEQ ID No.4 and mentions their medical and/or diagnostic use: see fragments in Table I which are within the domain (20-370).
The applicant has argued that D1-D3 indeed disclose the whole genome and its genes but do not disclose experimental verification of the activity of the present peptide NMB0928 and that it is not possible to predict which peptides can induce a cross-protective and cross-bactericidal response against a wide variety of meningococcal strains and that said

documents lack any support in its use as vaccine candidate.
The examiner acknowledges this reasoning and having regard to the experimental data demonstrating the immunological activity of NMB0928 novelty and inventive step is accepted for claims 6-8 directed to vaccines comprising said peptide. However the application lacks any support for an unexpected immunological activity of fragments of said peptide or a more general medical use of the peptide and said fragments. Hence in view of this prior art the independent claims 1,5,27,28 and 30 are considered to lack novelty under Art.33(2) PCT.

The related and/or dependent claims 2,3,9-26,29 and 31 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (see documents D1-D3, e.g., the corresponding passages cited in the search report).

II.Industrial applicability
For the assessment of the present claims 30-31 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.